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PATENT
Attorney Docket No. 204920

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James E. Ross Jr. et al.

Serial No. 09/100,100

Filed: 06/19/98

Group Art Unit: 3628

Examiner: Pedro R. Kanof

For: MEDICAL RECORDS,
        DOCUMENTATION TRACKING AND
        ORDER ENTRY SYSTEM

REPLY TO EXAMINER'S ANSWER UNDER 37 C.F.R. SECTION 1.193(b)(1)
AND
REQUEST FOR ORAL HEARING UNDER 37 C.F.R. SECTION 1.194

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

     This paper is filed in response to the Examiner's Answer mailed on December 16, 2003.

Appellants hereby respectfully request allowance of the pending claims for the reasons set forth in

Appellants' Appeal Brief filed on December 19, 2002; Appellants' Request for Reinstatement of the

Appeal and Supplemental Appeal Brief filed on June 24, 2003; and for the further reasons stated

herein.

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Appellants' Responsive Argument

    Appellants have carefully reviewed the Examiner's Answer and the references cited therein. For all the reasons previously stated, as well as the additional reasons recited herein, Appellants respectfully submit that neither Amado U.S. Patent No. 5,701,400, nor the Collen excerpts discloses or suggests the methods and systems recited in the currently appealed claims. The Answer, rather than concede such non-obviousness, attempts to broad-brush the rejection of each of Appellants' claims rather than addressing the claims on an element-by-element basis as mandated by Section 1208 10(d) of the M.P.E.P.

I.   Summary of Appellants' Claimed Invention

    Appellants' invention (see, e.g., claim 25) relates to methods and systems for generating medical reports that include sentences and paragraphs. The sentences and paragraphs are generated/compiled by a report rendering component. The report rendering component receives as input the previously stored "sentences and phrases related to medical data" and "patient data." The report rendering component thereafter renders reports from these two input types. Claim 37 has similar elements, and claims 42 and 55 are even more detailed in their recitation of the input sources for the report generator.

II.   Disclosure Summary of the Primary Cited References

    The Amado '400 patent is directed to, as stated in the ABSTRACT, "[A] system for applying artificial intelligence technology to data stored in databases and generates diagnostics that are user definable interpretations of information in the database." It is noted that the term "diagnostics", as defined in the Amado '400 patent, refers to "expert system results" (see, Amado, Col. 24, lines 17-18). The Amado '400 patent does not disclose any of the recited elements of the currently pending independent claims, that in all instances concern patient/medical data and text (paragraphs, sentences), rendered by a report rendering component, containing medical language.

    The Amado '400 patent, as indicated by its examples in the specification, is directed to business applications, such as customer service databases. The Amado '400 patent does not disclose generating reports including medical language sentences and paragraphs as recited in each of the currently pending independent claims. In fact, the only references to the medical field within the Amado '400 patent occur in the background of the invention (at col. 4, lines 44-47, and col. 6, lines 60-68). In a rather lengthy background, Amado acknowledges the existence of a number of expert systems and expert systems building tools (see, col. 2, lines 50-51) to debug and repair artificial intelligence-based medical diagnostic systems (see, col. 4, lines 44-47). Also in the Amado background, at col. 6, lines 60-68, under a section entitled "Neural Networks," the

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Amado patent acknowledges the known use of artificial intelligence to render diagnoses from stated medical symptoms. Nowhere does Amado suggest that its system generates medical language reports, comprising sentences and paragraphs, from patient data and stored sentences and phrases (as recited in claims 25 and 37).

The Collen reference describes a number of prior art hospital computer systems. Collen includes a section, at page 201, referencing retrieval of natural language reports. However, nowhere does Collen disclose or even remotely suggest generating such reports from a combination of sentences and phrases, and tabled patient data, to render Appellants' recited reports consisting of sentences and paragraphs.

III.   <u>Responsive Argument to the Answer's Grounds for Rejecting the Claims</u>

Appellants note that the Answer's grounds for rejecting the appealed claims are the same as the previously stated grounds in the Office Action dated December 6, 2002. Appellants incorporate by reference all previous arguments submitted in the original and subsequent appeal briefs. However, for the additional reasons set forth herein below, Appellants respectfully submit that, the Answer does not establish a *prima facie* case of obviousness, and therefore all of the pending claims, including independent claims 25, 37, 42 and 55, are patentable over the prior art.

A.   *The Answer Does Not Comply With Section 1208 10(d) of the M.P.E.P.*

As an initial matter, Appellants take exception to the form of the rejection of independent claims 25 and 37 as not being of a proper form mandated by subsection 10(d) of Section 1208 of the M.P.E.P. (8th edition, Rev. 1 published Feb. 2003) that requires:

> for each rejection under 35 U.S.C. 103, the examiner's answer, or single prior action, shall:
> (i) state the ground of rejection and *point out where each of the specific limitations recited in the rejected claims is found in the prior art* relied on in the rejection,
>
> ...
>
> (iii) explain how and why the claimed subject matter is rendered unpatentable over the prior art. If the rejection is based upon a combination of references, the examiner's answer, or single prior action, shall explain the *rationale* for making the combination.

The Answer does not meet the requirements under subsections (i) and (iii) recited above.

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The Answer does not follow the guidelines set forth under subsection (i) in the current case since the elements of independent claims 25 and 37 are treated as a single group (followed by a set of three citations to the Amado patent) in the grounds for rejection recited at page 3-4 of the Answer. The Answer similarly groups (or does not address at all) elements recited in claims 42 and 55. Thus, the Answer does not separately point out where each of the specific limitations recited in the rejected independent claims 25, 37, 42 and 55 is found in the disclosure of the Amado patent and Collen reference.

In the present case, due to the lack of applicability of the Amado disclosure to the claims and the general assertions recited in the grounds for the rejection, Appellants have been unable to pair elements of claims 25, 37, 42 and 55 with the disclosure of the Amado '400 patent. In particular, no embodiment of Amado's expert system, for digesting business data to render a diagnostics database, is configured to store patient data and related medical sentences and phrases. Nor does the Amado expert system create medical reports, comprising sentences and paragraphs, from the stored patient data and sentences and phrases. If the rejection of the currently pending claims 25, 37, 42 and 55 is not withdrawn, Appellants request supplementation of the Answer prior to oral argument (requested in a separate document submitted herewith) identifying the relevant portions of the Amado patent on an element-by-element basis with regard to claims 25, 37, 42 and 55.

Furthermore, the Answer does not meet the guidelines set forth under subsection (iii) with regard to specifying the *rationale* for making the combination. The Answer states that "[o]ne would be motivated to do that in order to increase the facility to enter and retrieval [sic] information stored in the system. However, the Answer does not explain *how* Collen's disclosure, if incorporated into the Amado expert system, would enhance Amado's input/output "facility." Appellants are unable to discern from the Answer: what is being incorporated from the Collen disclosure into the Amado expert system, how the disclosure is being incorporated, what actual system results from the combination, and the desirability of making such a system. Appellants respectfully submit that the Answer has not provided a "rationale" for making the combination upon which its obviousness rejection is based. In the event that the rejection of the pending claims is not withdrawn, Appellants request supplementation of the Answer prior to the oral hearing to more thoroughly describe the rationale for combining the Amado and Collen references.

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B.   *The Alleged Combination Does Not Support a Finding of Obviousness*

Appellants have identified, in previous arguments, the absence of disclosure of multiple elements in claims 25, 37, 42 and 55 in Amado and Collen, upon which the Answer bases the continued rejection of these claims. Appellants reassert such traversals of the claim rejections herein by reference. Notwithstanding the absence of multiple elements in the cited references, Appellants further submit that the prior art does not provide (and the Answer does not identify) sufficient *motivation* to incorporate any of the hospital computing systems identified in Collen into the Amado '400 patent.

By way of example, in support of the rejection of claims 25 and 37 the Answer, at page 4, states:

> "Amado does not explicitly disclose creating structured medical reports and stored sentences and phrases. Collen discloses such steps. (Page 199, line 17 – page 202, line 27). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to include such steps. *One would have been motivated to do that in order to increase the facility to enter and retrieval [sic] information stored in the system.*" [emphasis added]

A similar basis is recited in support of the rejection of claims 42 and 55 at the bottom of page 5 of the Answer.

The Federal Circuit has recently addressed the issue of what constitutes proper motivation for combining references. In the case of *In re Lee*, 61 USPQ.2d 1430 (Fed. Cir. 2002), the Federal Circuit held that obviousness rejections must be accompanied by well reasoned discussions of the rationale upon which the rejection relies. In the present case, the Answer relies upon a bare statement that one would be motivated to incorporate Collen's disclosure into the Amado expert system "to increase the facility to enter and retrieval information." The Answer does not explain how Collen's disclosure would be incorporated into Amado's database system. Nor does the answer describe the resulting system's functionality/desirability. Amado does not appear to have any deficiencies with regard to a user's ability to enter/retrieve information relating to its disclosed expert system for generating a diagnostics database. One cannot discern, based upon the present record, how incorporating Collen's teachings would *increase the facility to enter and retrieve information* on Amado's system, as asserted in the Answer. Thus, the stated motivation for combining the Amado and Collen references is inapplicable to the present case. For at least these additional reasons, the obviousness rejection of claims 25, 37, 42 and 55 is unfounded and improper.

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C.   *The Answer's Response to Argument for Group I Comprises a Series of Irrelevant Word Search Results Taken Totally Out of Context*

The numerous recitations, at pages 8-21 of the Answer, from the Amado patent do not disclose the medical report generation systems and methods defined in independent claims 25, 37, 42 and 55. In response to Appellants' argument that Amado does not disclose the claimed invention (that relates to *generating medical reports*), the Answer appears to report the results of an electronic word search of the Amado patent. This approach to addressing Appellants' argument would be no better had the Answer relied upon a word search of a dictionary. The numerous recitations to isolated words within the claims have minimal relevance to the claimed invention. The conclusion reached at the middle of page 21 of the Answer is thus unsupported by Amado's actual disclosure. This is especially true with respect to the Answer's assertion that Amado teaches generating reports, comprising sentences and paragraphs, rendered from patient data and stored sentences and phrases as set forth in the claims. The only references to the medical field in Amado describe (in the Background section) examples of prior art uses of expert systems.

Furthermore, the Answer, at page 21 asserts that Collen discloses the elements (recited in paraphrased form) of claims 25 and 37. However, the Answer, merely copies the contents of the Collen reference (see, Answer at pages 21-42) and does not state where each of the claim elements is disclosed in these copied excerpts. Among other shortcomings, none of the computer systems disclosed in Collen includes a report generator that renders medical reports including sentences and paragraphs that are rendered from tabled patient data and stored sentences and phrases related to medical data.

D.   *The Answer's Response to Argument With Regard to Group II Lacks a Showing of Motivation to Apply the References To A Medical Document Generator*

As an initial matter, Appellants note that the Ross Jr. et al. '948 patent is not prior art. The Ross '948 patent is the parent application of this now-appealed application. The other references are not related to medical records generation. Appellants thus submit that the Answer does not establish a basis for injecting the teachings of the cited Parker and Huttenlocker references into the teachings of the Amado and Collen references. For at least this reason, the Appellants traverse the rejection of the claims of Group II of this appeal.

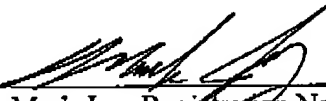In re Appln. of James E. Ross, Jr. et al.
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E.   *The Answer's Response to Argument For Group III Does Not Support An Obviousness Rejection With Regard To Claim Elements Relating To Generating a Triage Record*

Tallman does not disclose a method or system for generating a triage record as recited in claims 47 and 58. In response to Appellants' previous argument, the Answer, at pages 44-45, references disclosure of an interactive patient assessment stored program, including branched chain logic, that responds to input patient data to render a next assessment question for the person performing triage. As previously asserted, Tallman discloses a system for guiding a triage encounter. Tallman does not suggest or disclose that the responses obtained during the triage encounter are thereafter combined with stored sentences and phrases to render a triage report that includes sentences and paragraphs.

Conclusion

In both office actions preceding this appeal, in the subsequent Office Action, mailed on March 28, 2003, and the Answer mailed on December 16, 2003, there has been an absence of recognition that the claimed invention recites an invention including a method and system for generating medical documentation (e.g., a patient record) in the form of sentences and paragraphs, and wherein the sentences and paragraphs combine medical facts and supplemental language to provide context to the medical facts. The subject matter of the claimed invention is not obvious over the prior art known to Appellants. Accordingly, Appellants respectfully submit that the rejections of the pending claims do not present a *prima facie* case of obviousness and should be reversed.

Respectfully submitted,

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Date: February 12, 2004

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APPENDIX (APPEALED CLAIMS)

25.   A method for rendering a report including medical language from previously

stored data, said method comprising:

storing sentences and phrases related to medical data,

inputting patient data at a peripheral data input device,

transferring the patient data from the peripheral data input device to a server

communicatively coupled to the peripheral data input device and tabling the patient data at the

server,

transferring the tabled patient data from the server to a report rendering component, and

compiling sentences and paragraphs by the report rendering component from the stored

sentences and phrases and the patient data, whereby stored medical facts associated with the

input patient data are converted into sentence structure.

26.   The method of claim 25, further comprising rearranging the medical facts

compiled into sentence structure into a medically appropriate order.

27.   The method of claim 26, further comprising consolidating, by the report rendering

component, automatically generated medical English text with patient-related stored text.

28.   The method of claim 27, further comprising inserting, by the report rendering

component, headlines and sub headlines within the report.

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29.   The method of claim 27, further comprising modifying, in accordance with programmed report generation instructions, the font of text within particular portions of the report to use of bold, italic, and larger text sizes to emphasize important medical sections or information.

37.   A method for rendering a report including medical language from previously stored data, said method comprising

storing sentences and phrases related to medical data,

inputting patient data via a data input device,

transferring the patient data to a server and tabling the patient data,

transferring the tabled patient data to a report rendering component, and

compiling sentences and paragraphs by the report rendering component from the stored sentences and phrases and the patient data, and thereby converting stored medical patient data, including the input patient data, into medical facts in sentence structure.

38.   The method of claim 37, further comprising rearranging the medical facts compiled into sentence structure into a medically appropriate order.

39.   The method of claim 38, further comprising consolidating, by the report rendering component, generated medical text with patient-related stored text including dictated transcripts.

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40.   The method of claim 39, further comprising inserting, by the report rendering component, headlines and sub headlines in the generated medical text where appropriate.

41.   The method of claim 40, further comprising modifying, in accordance with programmed report generation instructions, the font of text within particular portions of the report to use bold, italic, and larger text sizes to emphasize important medical sections or information in the generated medical text.

42.   A method for computer-aided generation of patient medical documentation assembled from a combination of sources including user supplied text, system supplied pre-phrased text retrieved from a database in accordance with a specified pre-phrased text identifier, and text generated from input medical data facts, said method comprising the steps of:

associating multiple pieces of information regarding a patient with a patient medical information record, the multiple pieces of medical information comprising:

input text of the type generally arising from transcribed dictation,

pre-phrased text retrieved from an electronic data storage apparatus and associated with a pre-phrased text identifier, and

medical data facts,

wherein inputs relating to the multiple pieces of information regarding the patient are received by a medical information input interface providing random access to at least one of a set of medical information fields associated with the patient medical information record;

receiving an identification of a patient medical document type; and

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generating, by a computer system under software control, a patient medical document based upon at least a portion of the multiple pieces of information regarding the patient and an information specification corresponding to the patient medical document type identification that specifies the portion of the multiple pieces of information to be included in the patient medical document, said generating step comprising, in any order:

first inserting the input text at locations within the patient medical document in accordance with a text type associated with each distinguished portion of the input text,

second inserting text corresponding to the pre-phrased text retrieved from an electronic data storage apparatus, and

third inserting text generated in accordance with the medical data facts.

43.   The method of claim 42 wherein the text generated in accordance with the medical data facts is generated in accordance with a medically logical sequence.

44.   The method of claim 42 wherein the step of generating a patient medical document further comprises generating heading text in accordance with the patient medical document type designation.

45.   The method of claim 42 wherein the step of generating a patient medical document further comprises arranging the multiple pieces of information regarding the patient in accordance with the medical document type designation.

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46.   The method of claim 45 wherein the patient medical document is a patient medical report.

47.   The method of claim 45 wherein the patient medical document is a triage record.

48.   The method of claim 45 wherein the patient medical document comprises nurse notes.

49.   The method of claim 42 wherein the text generated in accordance with the medical data facts is medical text.

50.   The method of claim 42 further comprising providing an editing tool to modify specified pre-phrased text.

51.   The method of claim 42 further comprising providing a set of selectively activated input modules facilitating prompted input of information relating to care for a patient.

52.   The method of claim 42 further comprising providing a security mechanism facilitating limiting access to particular users.

53.   The method of claim 42 further comprising recording a time at which a particular piece of information is submitted for a patient medical record.

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54.   The method of claim 53 further comprising recording an identity of a logged on

user that supplied a particular piece of information stored in the patient medical information

record.

55.   A system for computer-aided generation of patient medical documentation

assembled from a combination of sources including user supplied text, system supplied pre-phrased

text retrieved from a database in accordance with a specified pre-phrased text identifier, and text

generated from input medical data facts, said system comprising:

computer executable database software for associating multiple pieces of information

regarding a patient with a patient medical information record, the multiple pieces of medical

information comprising:

input text of the type generally arising from transcribed dictation,

pre-phrased text retrieved from an electronic data storage apparatus and associated

with a pre-phrased text identifier, and

medical data facts,

wherein inputs relating to the multiple pieces of information regarding the patient are

received by a medical information input interface providing random access to at least one of a set

of medical information fields associated with the patient medical information record; and

computer executable document generation software for receiving an identification of a

patient medical document type, and in response generating a patient medical document based

upon at least a portion of the multiple pieces of information regarding the patient and an

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information specification corresponding to the patient medical document type identification that specifies the portion of the multiple pieces of information to be included in the patient medical document, said generating a patient medical document comprising, in any order:

first inserting the input text at locations within the patient medical document in accordance with a text type associated with each distinguished portion of the input text,

second inserting text corresponding to the pre-phrased text retrieved from an electronic data storage apparatus, and

third inserting text generated in accordance with the medical data facts.

56. The system of claim 55 wherein the computer executable document generation software includes software instructions for arranging the multiple pieces of information regarding the patient in accordance with the medical document type designation.

57. The system of claim 56 wherein the patient medical document is a patient medical report.

58. The system of claim 56 wherein the patient medical document is a triage record.

59. The system of claim 56 wherein the patient medical document comprises nurse notes.

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60.   The system of claim 55 wherein the text generated in accordance with the medical data facts is medical text.

61.   The system of claim 55 further comprising an editing software utility facilitating modifying specified pre-phrased text.

62.   The system of claim 55 further comprising a set of selectively activated input modules facilitating prompted input of information relating to care for a patient.

63.   The system of claim 55 further comprising a security mechanism facilitating limiting access to particular users.

64.   The system of claim 63 wherein the security mechanism includes executable software for recording an identity of a logged on user that supplied a particular piece of information stored in the patient medical information record.

65.   The system of claim 63 further comprising computer software for recording a time at which a particular piece of information is submitted for a patient medical record.

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EXAMINER PEDRO R. KANOF
GROUP ART UNIT: 3628

TELEPHONE NUMBER:
FACSIMILE NUMBER: (703) 872-9306

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3.5.04

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

</div>

In re Application of:

James E. Ross Jr. et al.

Application No. 09/100,100   Art Unit: 3628

Filed: 06/19/98   Examiner: Pedro R. Kanof

For: MEDICAL RECORDS,
       DOCUMENTATION TRACKING AND
       ORDER ENTRY SYSTEM

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TRANSMITTAL OF APPELANTS REPLY TO EXAMINER'S ANSWER UNDER
37 C.F.R. SECTION 1.193(b)(1) AND REQUEST FOR ORAL HEARING
UNDER 37 C.F.R. SECTION 1.194

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Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.193(b)(1), appellants hereby submit Appellants' Reply to Examiner's Answer in triplicate.

The items checked below are appropriate:

1.   **Status of Appellants**

This application is on behalf of ☐ other than a small entity or ☒ a small entity.

2.   **Oral Hearing**

       ☒   Appellants request an oral hearing in accordance with 37 CFR 1.194.

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3.   **Extension of Time**

        ☒   Appellants believe that no extension of time is required. However, this conditional petition is being made to provide for the possibility that appellants have inadvertently overlooked the need for a petition and fee for extension of time.

                         Extension fee due with this request: $

4.   **Total Fee Due**

The total fee due is:

Brief on Appeal Fee	$ 0.00
Request for Oral Hearing	$145.00
Extension Fee (if any)	$ 0.00

                         Total Fee Due: $145.00

5.   **Fee Payment**

        ☐   Attached is a check in the sum of $.
        ☒   Charge Account No. 12-1216 the sum of $145.00. A duplicate of this transmittal is attached.

6.   **Fee Deficiency**

        ☒   If any additional fee is required in connection with this communication, charge Account No. 12-1216. A duplicate copy of this transmittal is attached.

Mark Joy, Reg. No. 35,562
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Date: February 12, 2004

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